EXHIBIT 12

Community Oncology Alliance

DEDICATED TO EXCELLENCE IN CANCER CARE IN THE UNITED STATES

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HAND-DELIVERED

December 7, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS – 1429 – FC

Dear Dr. McClellan:

To follow up and supplement the comments submitted on November 16, 2004, the Community Oncology Alliance ("COA") is submitting additional comments to the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005," which was published in the Federal Register as a Final Rule with Comment on November 15, 2004. This comment letter only addresses the transition required to implement the Medicare Part B changes. We plan to submit comments on the data and methodology used to compute the reimbursement policy changes and address the issues raised in the recently released Government Accountability Office ("GAO") report, under separate cover.[1]

As you know, in enacting changes to the Medicare Part B reimbursement methodology through the Medicare Modernization Act ("MMA"), Congress sought to change the current system that overpaid for cancer drugs but underpaid for essential drug administration and related medical services. COA was created to support and advocate for Medicare reform that is balanced between drugs and services but is reflective of the realities of modern-day cancer care. Unfortunately, the Medicare system has not kept pace with the increasing complexity and cost of treating cancer.

The stark, indisputable reality is that community cancer clinics, payers (i.e., Medicare primary and secondary payers; other commercial payers), and the Centers for Medicare and Medicaid Services ("CMS") are simply not ready to

[1] Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Providers' Costs issued by the GAO on December 1, 2004.

implement the Medicare changes for 2005. These are revolutionary changes in Medicare reimbursement and, with 17 business days before implementation, there is no guidance and/or education to payers and community cancer clinics regarding processes and procedures. Neither payers nor clinics will be afforded sufficient time to make the necessary system adaptations and, with so little time remaining, this is now virtually impossible. Additionally, because the appropriate systems and safeguards will not be in place, we believe the claims for payment pursuant to the policy changes will not be compliant with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and thus, these claims will be delayed or denied, which will be absolutely devastating to community cancer clinics. Furthermore, it must be emphasized that never before have changes of this magnitude — and there have only been a few changes of this magnitude for cancer care — been implemented with so little time and guidance and without a transition or grace period.

We base these assertions on numerous discussions with all types of payers, including CMS, as well as community cancer clinics across the country. Exhibit 1 details the problems, issues, and questions, all of which make implementation of the Medicare reimbursement changes virtually impossible. The amount of uncertainty among payers and providers is so great that there is already mass confusion. Unfortunately, regardless of whether CMS is able to provide the required and essential guidance and education, with only 17 business days remaining until the MMA changes are scheduled to be enacted, it is virtually impossible to have the necessary systems in place. In fact, we are very concerned that the lack of time to implement the proper electronic systems will result in claims delayed or denied because of noncompliance with HIPAA. Additionally, we believe that the lack of time to modify/install electronic claims processing systems–will make temporary but costly and time-consuming paper systems a necessity. The Medicare changes to both drugs and services will force an inordinate burden on community cancer clinics to process paper claims.

Cancer care is facing a true crisis. Unfortunately, because private payers generally follow Medicare reimbursement, the Medicare changes impact all of cancer care in this country. As a result, as the largest payer of cancer care, Medicare has a responsibility to carefully consider the ramifications of its actions.

COA has committed to CMS, as recently as last week in a meeting COA representatives had with key CMS personnel that it will work with CMS on education and guidance to the cancer community. We are dedicated to Medicare reform. The steps that CMS has taken are truly in the right direction. However, the reality of the magnitude of the MMA changes is such that there is simply not sufficient time.

Short of emergency action by Congress, COA has carefully analyzed these issues and has looked to precedent to identify a way for CMS to comply with the law without risking the devastation of cancer treatment in this country. Specifically, COA notes that when CMS has had to implement major changes affecting health care reimbursement in prior years, CMS has delayed implementation (but not the effective date) to ease the impact on providers, avoid chaos in the health care industry, and above all, not disrupt patient care. For example, CMS has exercised its authority and discretion in the past by allowing the health care industry to utilize and submit transaction code sets that are not compliant with HIPAA even after the October 16, 2003,

deadline. Similarly, CMS not only established the 2003 Medicare physician fee schedule effective March 1, 2003 (rather than January 1), but also continued to pay physicians under the higher 2003 rates for claims for services rendered before March 1 but submitted and processed after March 1. Furthermore, CMS again exercised its authority and discretion by rescinding its proposal to subsequently reconcile the overpayments.

Accordingly, COA notes that existing authority and discretion to update and revise the physician fee schedule conveyed to CMS under section 1848 of the Social Security Act ("SSA") permits CMS to adopt the following solutions:

- To ease the impact of the physician fee schedule changes on the practice of community oncology, CMS can accept 2004 codes for oncology services through 2005 for as long as necessary to provide accurate, thorough guidelines and to allow for proper implementation and systems, and retroactively reconcile payments under the 2005 codes effective January 1, 2005.

- To ease transition of the average selling price ("ASP") methodology, CMS can maintain the 2004 drug payment method through 2005 for as long as needed to obtain verifiable, accurate, and stable ASP data, and retroactively reconcile payments under the ASP method effective January 1, 2005. As detailed in our comment letter of November 16, 2004, there are numerous problems with the accuracy and implementation of the Medicare drug reimbursement changes based on ASP.

Once again, COA is committed to balanced, equitable Medicare reform. However, we believe that cancer care now faces a crisis because, regardless of the debate surrounding the adequacy of payments, the Medicare changes are not ready to be implemented. In order to avoid disruption of cancer care in this country, harm to seniors covered by Medicare, and possible violations of HIPAA, COA is requesting that CMS transition the implementation of the MMA provisions relating to Medicare Part B.

There has never been a more compelling time and reason to exercise your authority and discretion to establish a transition period. Is the rush to save Medicare a paltry $350 million for 2005 — in terms of trillions of dollars of federal spending for 2005 — worth the risk of displacing cancer patients and dismantling the cancer care delivery system in this country?

There is a need for urgent leadership from the Administration and the Congress. After all, cancer is a disease that impacts all of us in one way or another.

Sincerely,

Kurt Tauer, MD, President
Leonard Kalman, MD, Vice President
Frederick M. Schnell, Secretary
Community Oncology Alliance

cc: Mr. Ira Burney (CMS/OL)
Mr. Marc Hartstein (CMS/CMM/HAPG)
Mr. Herbert Kuhn (CMS/CMM)
Mr. Bob Loyal (CMS/OFM/PIG/DPE)
Mr. Jim Menas CMS/CMM/HAPG/DPS)
Ms. Carolyn Mullen (CMS/CMM/HAPG/DPS)
Mr. Stephen Phillips (CMS/CMM/HAPG/DPS)
Ms. Liz Richter (CMS/CMM/HAPG)
Mr. Don Thompson (CMS/CMM/HAPG/DAS)

Exhibit 1

Problems and Issues with the Implementation of Medicare Part B Changes to Cancer Care Reimbursement on January 1, 2005

Problems and Issues with the Implementation of Medicare Part B Changes to Cancer Care Reimbursement on January 1, 2005

Prepared by the Community Oncology Alliance (COA)
Cancer Care Comprehensive Coding Task Force
December 6, 2004

General Comments

1. **There is not adequate time to conduct the necessary education of providers (i.e., community cancer clinics) on the historic Medicare coding and billing changes.**

   There are currently only 17 working days before implementation of historic changes to the way that the Centers for Medicare and Medicaid Services (CMS) reimburses community cancer clinics for cancer drugs and medical services provided to seniors covered by Medicare. These changes include a CMS demonstration project to assess certain cancer-related symptoms, new drug administration codes, and a new drug reimbursement system based on average selling price (ASP). The changes require coding guidance, documentation requirements, and coverage guidelines from CMS. None of these have been released to date by CMS. While the Final Rule (CMS – 1429 – FC) intimates some of these parameters, it is not explicit. Changes of this historic magnitude require thorough education and guidance from CMS, especially given the grave consequences of disrupting cancer care to millions of seniors covered by Medicare.

2. **Likewise, there is not adequate time to educate carriers. This means that reimbursement claims will be delayed, denied, or paid incorrectly. This will create a cash flow crisis for community cancer clinics.**

   Many community cancer clinics across the country have contacted their Medicare carriers for clarification of the documentation and coding guidelines for these historic coding changes. Carriers have informally either stated that they do not understand these changes or have provided erroneous information based on the HCPCS table errors, which will be explained later in this document. Practically, this means in January 2005 that claims will be delayed, denied, and/or paid in error. Additionally, while this will negatively impact community cancer clinics, it will have a profound financial impact on your Medicare carriers and their ability to conform to CMS payment deadlines.

3. **Most commercial and secondary payers will not honor the demonstration project or the G-codes. This will result in increased bad debt and financial strain on community cancer clinics.**

   When coding changes are issued without formal CPT indexing, notating, and instructions, this results in Medicare secondary payers and other insurers not paying for their portion of the claim. We have met with numerous Medicare secondary payers as well as commercial (private) payers. Virtually every secondary payer has stated that they will not reimburse for

the demonstration project. Moreover, many commercial and secondary payers have also stated that they will not use the new G-codes, which they view as a coding system with a one-year life span. Both of these issues will have a serious financial impact on cancer care. Community cancer clinics will incur an automatic 20% or $60 million bad debt on the demonstration project. Additionally, payers' refusal to use the G-codes will require a costly, time-consuming, and burdensome paper-based translation claims processing system for the new drug administration codes. The new cost of this paperwork and paper-based system has not been factored into the financial projections by CMS as to the impact of Medicare reimbursement changes on community cancer clinics. While CMS is charged with only Medicare management, the Medicare coding changes have a strong multiplier effect throughout the payer community, especially since Medicare is the largest single payer for cancer care.

4. **The lack of payer adherence to one coding system may lead to serious HIPAA violations by both payers and providers.**

   HIPAA requires that providers and payers communicate via electronic claims processing in specific formats. Due to the fact that secondary payers will likely not pay for G-codes throughout 2005, many claims will have to drop to paper and be submitted by mail. This is certainly against the spirit of HIPAA and will result in security, claims processing, and privacy violations.

Specific areas of concern with reference to both the new drug administration codes and to the Demonstration Project are outlined in the following sections.

Drug Administration Coding and Billing (G0345-G0363)

5. **The HCPCS table was released to the Medicare carriers on October 13 with serious errors and must be totally revised by CMS immediately.**

   There are three major errors (G0348, G0350, and G0360) in the HCPCS that we discovered. As verified by CMS personnel, these errors have been passed onto Medicare carriers in the tape that was submitted on October 13 and this issue will result in claims rejections and an overall misunderstanding of CMS' intentions for these codes as stated to us and other members of the cancer community. The resultant rejections will cause community cancer clinics further confusion and administrative cost. There has been no commitment by CMS as to when these errors will be corrected.

6. **There is not adequate time to update/load/test software packages for both community cancer clinics and carriers.**

   The new drug administration codes are effective for dates of service after January 1, 2005. This means that community cancer clinics will be running two billing systems — just for Medicare. Medicare carriers have stated that they will have to manually force some claims from their systems as the new coding parameters violate edits currently in their software or scanners. After first quarter 2005, for clinics, there will need to be an electronic crosswalk

between CPT and the new HCPCS. This is an expensive process that has a life span of 12 to 18 months. Given all the problems associated with the implementation of HIPAA, especially in terms of software changes, there is not adequate time to load and test new software systems/solutions on the clinic end. We have been told that carriers are having similar problems.

7. **CMS has not committed to clinical guidelines for new codes that necessitate clinical input for correct documentation and payment.**

   There are new codes for hormonal injections (G0355-G0356), hydration (G0345-G0346), and concurrent infusions (G0350). All of these require better definition for cancer care clinicians to feel comfortable billing them to Medicare carriers. CMS has left this task to the carriers, who have yet to be educated by CMS. This will lead to misinformation and misinterpretation.

8. **CMS has not issued simple claims submission guidelines to ensure that community cancer clinics have any likelihood of filing a clean claim on January 1, 2005.**

   The multiplicity of coding choices for drug administration may cause confusion as to how codes actually match up with individual drugs administered on a single date of service. These are just some examples of the questions that need to be answered in formal guidance by CMS:

   - Do the drugs and drug administration codes need to be on the same electronic page?
   - Will there be limitations on codes submitted by drug?
   - Will there be a match up of specific J-codes and drug administration or match up of diagnosis with drug administration codes?

The Demonstration Project (G9021-G9032)

9. **It is totally unclear how the three G-codes for the demonstration project will be paid by Medicare.**

   Examples of the questions that need to be answered in formal guidance provided by CMS:

   - Will they be paid on a one-third basis?
   - Will they be paid on the last code in the series?
   - What instructions should patients be given about the demonstration and why they are being asked to pay $26 (their 20% co-payment on the $130 per assessment charge) for each time they provide data to CMS. Typically, patients are paid for providing data.

   We were told by CMS that these are ‘operational’ issues. That is true, but the livelihood of community cancer clinics depends on precise information provided by CMS regarding the payment format of these demonstration codes. There is tremendous confusion about how to charge for these codes.

10. **The 20% co-payment with the G-codes will not be covered by Medi-Gap. Some carriers will not even reimburse for the demonstration project as the primary Medicare payer.**

    Medicare does not have any jurisdiction over the secondary payers to enforce the rule to reimburse Medicare-covered services. Private payers have stated verbally and in writing across the country that they will not pay the co-payment for any CMS demonstration project. Furthermore, we have heard from some private payers with primary Medicare HMOs plans that they will not cover the demonstration project even as the primary payer.

11. **There are no formal documentation guidelines from CMS regarding proof that the patient was asked the demonstration project questions.**

    While we strongly believe that an electronic or paper form with the questions will suffice, this has not been confirmed by CMS. Is CMS under any requirements in this project to collect primary data? If so, what data will CMS have to collect and when will they have to collect it? It is very difficult to recapitulate primary data when it has not been required from the outset.

Average Selling Price

12. **There will be confusion regarding billing for drugs under the new ASP system, especially since the drug reimbursement rates effective January 1, 2005, have not yet been released by CMS.**

    Anytime there has been an adjustment to the Medicare drug reimbursement system, there is confusion and problems that result in delayed or denied payment claims. This was true at the beginning of 2004 when all that happened was simply a reduction in the reimbursement rate but not a change in the basic system (i.e., change from a payment rate of 95% of average wholesale price (AWP) to 85% of AWP). There will be confusion regarding billing by NDC, units, etc.

The problems raised in this document will lead to rejection of claims by the primary Medicare payers, secondary Medicare payers, and other payers. The lack of concrete educational efforts will further complicate the payer acceptance and understanding of the new codes. To add to the confusion, CMS is prohibited from dictating medical policy to all of the carriers. Moreover, CMS has no jurisdiction to require that private payers use Medicare-generated codes where there are substitutions in CPT. CMS has told us that in essence we will all learn as we proceed. Without the edits from CMS, we will never know if we are being paid the proper reimbursement amount. Without guidelines from CMS, the carriers will not know if they are reimbursing the proper amount or denying claims that should legally be paid. While we appreciate the enormity of these tasks, lack of prospective action will lead to chaos and financial hardship for community cancer clinics. This will impact patient care for seniors covered by Medicare. In cases, we believe that clinics will face a cash crisis that will halt cancer treatments.